Chapter 9: Site-Specific Data Versus Default Factors

9.1 Introduction

In the absence of site-specific information (e.g., contaminant characterization, exposed population factors, etc.), the best choice for describing the actual exposure and risk outcome is by using a combination of factors chosen by the risk assessor. Quantifying exposures is rooted in the use of professional scientific judgement. Improving basic research in the various science branches and its application in the environmental field will inevitably reduce uncertainty in risk estimates.

The need at EPA for greater consistency among various sites has led to the development and evolution of guidance documents that provide agency-wide standard default factors and procedures to be used in the absence of site-specific values. EPA responded to arguments that standard default factors are conservative saying that, in the absence of (or limited) data, the risk estimates should be protective of public health.

9.2 Discussion of Site-Specific Data Versus Default Factors in Statutes, Regulations, and Guidelines

9.2.1 Statutes and Regulations

CERCLA, SARA, and NCP do not provide specific guidance on how to address the absence of site-specific data when performing baseline risk assessments. However, the documents provide general directives regarding risk assessments.

9.2.2 Guidelines

Guidelines for Estimating Exposures

The Federal Register of September 24, 1986, published the final EPA Guidelines for Estimating Exposures (USEPA, 1986a), as well as the responses to comments by the public and by the EPA Scientific Advisory Board (SAB). The guidelines, which provide EPA with a framework for performing exposure assessments, indicated that the ideal exposure assessment would be based on data derived from environmental measurements, but recognized that data gaps would be a common problem. When environmental data are limited they direct that modeling be used to estimate exposures and that properly identified assumptions and "order of magnitude estimates" be utilized to delineate exposure areas of concern (USEPA, 1986a).

The guidelines state that uncertainty evaluation is an important part of all exposure assessments because both data and assumptions carry varying degrees of uncertainty that impact the accuracy of exposure assessments. The guidelines recognize the existence of uncertainties in measurements of environmental contamination, and in the estimation of those concentrations when direct measurements are

unavailable. They state that "reliable, analytically-determined values must be given precedence over estimated values" (USEPA, 1986a).

Commentors expressed concern that the guidelines allow assessors "too much latitude in choice of approach and do not assure that all data, sources, limitations, etc., are considered before an exposure assessment is conducted." EPA replied that the generality of the guidelines is deliberate "in order to accommodate the development of exposure assessments with different levels of detail depending on the scope of the assessment." Other commentors asked for further guidance to address situations where different exposure models give different results. EPA indicated the necessity of evaluating the uncertainties associated with source data and assumptions, "whether the exposure assessment is based on measurements or simulation model estimates" (USEPA, 1986b). EPA also replied to concerns that worst-case estimates would be used when data are limited or nonexistent "The guidelines do not encourage the use of worst-case assessments, but rather the development of realistic assessments based on the best data available" (USEPA, 1986b). However, the guidelines emphasize that EPA will err on the side of public health when evaluating uncertainties if data are limited or nonexistent.

Superfund Public Health Evaluation Manual (SPHEM)

The Superfund Public Health Evaluation Manual (SPHEM) was published in October of 1986 to provide detailed guidance on how to conduct a public health evaluation at a Superfund site. Because the actual dose received is generally uncertain, the exposure assessment requires the use of complex exposure models that are based on incomplete knowledge of how hazardous substances are transported and undergo transformation in the environment, and how they affect human health. SPHEM indicates that the most appropriate models for Superfund sites are "simple environmental fate models using conservative (i.e., reasonable worst case) assumptions" (USEPA, 1986b).

SPHEM outlines estimation methods for determining indicator chemical concentrations when actual data are not available on the extent and duration of human exposure before remediation. Although the approach was toward "worst-case" scenarios, SPHEM also indicates that "this conservative approach can be modified based on site-specific information to the contrary," and that "if more accurate site-specific information is available, it can be used to give a better representation of risk at the site" (USEPA, 1986b). In addition, SPHEM provides several examples of how to use the standard assumptions and how to make adjustments based on more accurate site-specific data (e.g., intake and body weight information for the exposed population). Following are SPHEM guidelines on this topic:

- "It is essential to collect sufficient environmental sampling data so that if contamination has reached a human exposure point, some actual data may be used in the evaluation of potential effects."

- "At most sites, a combination of site monitoring data and environmental modeling results will be required to estimate chemical concentrations at exposure points."

- "...at all sites the available monitoring data must be reviewed thoroughly and used to the extent possible. For example, monitoring data should always be used to assist in

> selection, calibration, and verification of chemical fate models and to help in the estimation of source terms (i.e., release rates) for these models."

SPHEM also recommends that risk assessment consult other sources of site-specific information. In the case of determining human exposures, SPHEM states that "in the event that data from human monitoring in the site vicinity (e.g., blood or tissue analyses, genetic testing data) are available or such monitoring is planned, the Agency for Toxic Substances and Disease Registry (ATSDR) should be consulted. ATSDR should take the lead in conducting any human monitoring and in assessing the current health status of people near the site based on human monitoring data" (USEPA, 1986b).

Superfund Exposure Assessment Manual (SEAM)

SEAM, published as a final document in April of 1988, provided guidance for assessing contaminant release, environmental fate and transport, and human exposure to contaminants emanating from hazardous waste sites. SEAM was developed to give consistency in conducting exposure assessments at Superfund sites. It compiled and integrated various methodological approaches published by EPA and others.

SEAM recognizes that the approach to conducting exposure assessments is conservative: "While it is traditional in exposure assessments to make conservative assumptions in the absence of data, such assumptions must be reasonable . ..." However, it warns of the possibility that multiple conservative assumptions may result in extreme and unrealistic assessments: "Use of reasonably conservative assumptions at each step may produce cumulative assessment results that are overly conservative and thus unreasonable."

SEAM provides analytical procedures supplementing SPHEM. According to SEAM the procedures were intended to be flexible, as illustrated in the following passage:

> The user of this manual should understand that these analytical procedures are intended to be applied site-specifically. No two sites will be exactly alike in terms of the extent and complexity of contamination, of contaminant migration, or of potentially exposed populations. Therefore, the specific analytical procedures to be applied in all Superfund exposure assessments cannot be freed in general. Instead, the approach and methods applied to conducting an exposure assessment must be tailored to address existing site conditions (USEPA, 1988b).

Risk Assessment Guidance for Superfund, Volume I (RAGS)

RAGS, published in December of 1989, constitutes the present conceptual framework for CERCLA risk assessments. The exposure assessment process and the quantification of exposures is delineated in RAGS as follows: "...the exposure assessor calculates chemical-specific exposures for each exposure pathway. Exposure estimates are expressed in terms of the mass of substance in contact with the body per unit body weight per unit time" (USEPA, 1989a). RAGS states that the selection of exposure factors in CERCLA exposure assessments should result in "an estimate of the reasonable maximum

exposure" (USEPA, 1989a). RAGS also indicates that "...a determination of 'reasonable' cannot be based solely on quantitative information, but also requires the use of professional judgment. "

The Exposure Factors Handbook (EFH)

The Exposure Factors Handbook (EFH), intended to serve as a support document to the EPA's 1986 Guidelines for Estimating Exposures, provides basic equations for estimating exposure for various exposure scenarios. The EPA's guidelines for estimating exposures, as delineated in SEAM, were expanded and improved in EFH (USEPA, 1989b). The guidelines were developed to promote consistency among the various exposure assessment activities, and toward standardizing exposure assessment calculations. The handbook demonstrates how to apply standard default factors to specific exposure scenarios when site-specific data are not available. For each scenario, the handbook provides the following:

- the basic equation for estimating exposure;
- recommended default values for each parameter in the exposure equation (the default values are presented as averages [intended to represent typical values], ranges [derived from distributions, where possible, basing the lower end on the 50th percentile and the upper end on the 90-95th percentile], and frequent y distributions); and
- justification for each recommended value.

The EFH points out that the analyst "needs to be aware of uncertainties that result from using conservative assumptions when data are lacking," and that when it is not feasible to acquire measured release rates, assessors could base estimates on contaminant concentration measurements in relevant source media (e.g., basing an estimate of groundwater contaminant concentration on measured concentrations in contaminated soil) (USEPA, 1989b). EFH reminds the risk analyst that no two sites are identical in the nature and extent of contamination. Therefore, the analytical procedures applied in each assessment should be site-specific.

Research to Improve Health Risk Assessments (RIHRA)

Concerns raised about uncertainties and how assumptions are made in risk assessments prompted the establishment of EPA programs and revisions of guidance documents. One of the programs established by EPA was labeled Research to Improve Health Risk Assessments (RIHRA). The program's primary objective was to identify the factors that produced the variability and uncertainty in Superfund exposure assessments. RIHRA published a report entitled "Exposure Assessment at Superfund Sites" (USEPA, 1989c). The report observed that SPHEM and SEAM were considered the "primary guidance documents relied [upon] most exclusively by the EPA regional offices" for use in preparing CERCLA risk assessments. Deficiencies in the guidance documents were supplemented by the EPA regions with open scientific literature, communications with EPA headquarters, contractors, etc. In addition, the RIHRA report identified supplemental guidance documents prepared by EPA Region I.

Supplemental Guidance to RAGS: EPA Region I Guidance

Responsibility for determining and explaining the guidance rationale for the exposure assumptions fell on the various EPA regional administrators. EPA Region I (Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont), for instance, formed a Risk Assessment Group that released the "Region I Supplemental Manual to Risk Assessment Guidance for the Superfund Program" (USEPA, 1989d). As with SPHEM and SEAM, this guidance provided for a reportable range of exposure values, but it also called for a greater imperative to communicate and substantiate exposure assumptions and choice of exposure parameters. While no attempt was made to clarify terms such as "reasonable," Region I guidance provided for a set of default exposure parameters and recommended more communication with EPA remediation project managers (RPMs). The suggested default factors were to be used in the absence of site-specific data.

Supplemental Guidance to RAGS: Standard Default Exposure Factors

An EPA risk assessment intra-agency group was formed in March of 1990 "to address concerns regarding inconsistences among exposure assumptions in Superfund risk assessments." This group released an interim final document entitled "Supplemental Guidance to RAGS: Standard Default Exposure Factors" (USEPA, 1991a). According to the EPA intra-agency group, the principal reasons for the inconsistencies among exposure assessments included:

- factors derived from site-specific data,
- professional judgment when choosing values for key variables, and
- assumptions based on limited data.

The document provides further guidance on which specific default exposure factors to use when site-specific data are unavailable. It also states that "for factors where there is a great deal of uncertainty, a rationally derived conservative estimate is developed and explained" (USEPA, 199la). The standard set of default exposure values follows the 1990 NCP directive for quantifying exposures under RME scenarios.

EPA Superfund 30-Day Task Force

Concerns raised about CERCLA exposure assumptions resulted in the creation of the EPA Superfund 30-Day Task Force. The role of this task force was to improve the effectiveness of the CERCLA program. The 30-Day Task Force published the report "Accelerating Superfund Cleanups and Evaluating Risk at Superfund Sites" where it recommended the review of CERCLA risk assessment guidance and policies (USEPA, 199lb). To reduce the uncertainty inherent in risk assessments, the Task Force indicated the need for several groups to review the assumptions, including EPA's Office of Research and Development the Risk Assessment Council, the Science Advisory Board, as well as industry and environmental groups.

Exposure Assessment Methods Handbook (EAMH)

The Exposure Assessment Methods Handbook provides guidance to exposure assessors on methodologies to estimate concentrations of chemicals in the environment (USEPA, 199lc). This document indicates the need to "provide decision makers with the complete spectrum of information concerning the quality of a concentration estimate, including the potential variability in the estimated concentration, the inherent variability y in the input parameters, data gaps, and the effect these data gaps have on the accuracy or reasonableness of the concentration estimates developed" (USEPA, 199lc). The EAMH advises assessors to identify and prioritize "microenviroments" at a given site for exposure determination, as discussed in the following passage.

> Total human exposure assessment methodologies are often limited by the simplistic nature of developed exposure scenarios and frequently-used default values for input parameters. Such simplified approaches may not always account specifically for variations in exposure parameters or for the multitude of microenvironment in which people are exposed via a given exposure pathway and a given exposure route on a daily basis. Prioritization of microenvironment for an exposure assessment is dependent on human activities (i.e., durations and frequencies of exposures in different microenvironment), pollutant concentrations encountered in these microenvironment, and exposure parameters such as inhalation rate that vary according to microenvironment and associated activities. (USEPA, 199lc)

EAMH suggests examining human activity patterns and time-use studies to gather the information needed to select exposure pathways. The handbook also states that "when such information is not readily available, a conservative approach that accounts for all potential exposure routes should be taken" (USEPA, 1991c).

An SAB Report: Superfund Site Health Risk Assessment Guidelines

This SAB report (USEPA, 1993) was published as a result of an SAB meeting on April 7-8, 1992, in Bethesda, Maryland. The meeting was organized to review key issues related to RAGS. One of the report's conclusions was that the interpretation of an exposure value resulting from combining arithmetic average concentrations at a site with 50th and 90th percentile values for some of the default factors is very difficult to conceptualize. The SAB report recommends that in the absence of further guidance regarding the quantification of exposures at Superfund sites, the risk assessor should present a range of risk estimates.

9.3 Issues and Regulator Dialogue

9.3.1 Site-Specific Data versus Default Factors Issues

CERCLA guidance documents revealed that the evaluation of hazardous waste sites is characterized by numerous sources of uncertainty. The branches of scientific knowledge involved in evaluating human health risks from exposures to contaminants emanating from hazardous waste sites do

not yet provide for definite conclusions. This inability stems from the sources of uncertainty being rooted in the dynamic variability associated with natural systems, with the individual variability among the human population related to behavior and physiology, and with the assumptions made when filling data gaps in required information.

The guidelines for exposure assessment, as delineated in SEAM, EFH Guidelines for Exposure Assessment, and other documents, were developed to promote consistence y among EPA exposure assessment activities. The parameters used in exposure intake calculations have often been revised by EPA to underline new policies and default factors to be followed in CERCLA risk assessments. Following are the issues related to the use of site-specific data versus standard default values:

Limited Site-Specific Data Warrants the Use of Conservative Default Factors

The current policy guiding CERCLA risk assessments is the RME (see Chapter 4 of this guidance). The RME definition and applicable policies are found in Guidelines for Exposure Assessment (USEPA; 1992a). The Supplemental Guidance to RAGS: Calculation of the Concentration Term (USEPA, 1992b) and Supplemental Guidance to RAGS: Standard Default Exposure Factors (USEPA, 1991a) are also consulted to provide a better understanding of practical issues in the RME. The first document shows how the concentration term in the RME equation is calculated using the 95% UCL on the mean, explains the significance of the RME, and discusses the basic concepts concerning the concentration term. The Supplemental Guidance to RAGS: Standard Default Exposure Factors provides for the standard default exposure factors to be used in the Superfund program. The exposure factors in this guidance are considered the most appropriate, and are intended to be used under the RME scenario.

The National Resources Defense Council and the Environmental Defense Fund have declared in the popular press that assumptions contained in Supplemental Guidance to RAGS: Standard Default Exposure Factors result in "abandoning the reasonable worst-case scenario" and provide "less protection to the public" (BNA, 1991). However, the Chemical Manufacturers Association indicated that a "30-year exposure duration is a more reasonable assumption than 70 yearn," and views the guidance as a "step in the right direction, moving toward a more realistic worst-case assumption" (BNA, 1991). The EPA rationale for the new default values to be used when site-specific information is lacking was designed "to facilitate more consistent evaluation of the risks posed by the Superfund sites," and the guidance "attempts to reduce unwarranted variability" (USEPA, 1991a).

Responding to public comments expressing concerns that worst-case estimates would be used as a result of conservative default factors when data are limited or absent, the EPA stated in Guidelines for Estimating Exposures (USEPA, 1986a) that "the Guidelines do not encourage the use of worst-case assessments, but rather the development of realistic assessments based on the best data available. However, the Agency will err on the side of public health when evaluating uncertainties when data are limited or nonexistent. "

Site-Specific Data are Preferred to Standard Default Factors

A memorandum from the former Assistant Surgeon General Richard Guimond released in March of 1992 indicated that EPA CERCLA risk assessments relied "heavily on site-specific assessments of human and environmental risk in determining the need for remedial action, in identifying contaminants of concern and critical exposure pathways, and in determining protective cleanup levels" (USEPA, 1992c). Guimond suggested that the EPA rationale be based on the belief that site-specific circumstances provide more appropriate decision-making in protecting populations from site contaminants. The following passage from Guimond's memorandum highlights the issue:

> Superfund guidance indicates that valid site-specific information on exposure factors --particularly human behavior patterns--be used in exposure assessments, In the absence of site-specific survey data, or in cases where the assessment must examine projected changes in land use, guidance has relied on survey data for other populations, commonly at the national level. Is this approach reasonable?

EPA has recognized that risk assessments "are sometimes delayed because of the need to collect better sampling data, or negotiations with potentially responsible parties over land use, exposure assumptions, and chemical toxicity" (USEPA, 1992c). To address the need for more efficient risk assessments, CERCLA guidance documents have evolved toward a full description of risk wherein quantitative estimates are associated with characterization of uncertainty. However, consideration must be given to how greatly the risk estimates may vary depending on whether site-specific data or default values are used. For example, the following specific situations may require different data:

- High-risk populations may warrant use of site-specific data in place of national data.
- Recreational activities (e.g., fishing) may warrant use of surveys.
- Monitoring of background samples is necessary when natural or other suspected sources of contaminants may contribute to overall risk.
- Monitoring of water supplies and water distribution points may be necessary.

9.3.2 Regulator Dialogue

In many cases it may be worth the extra expenditure of resources to increase the amount of site-specific data available for use in a given risk assessment. Because they typically are conservative, the use of default factors because of a lack of site-specific data often results in overestimation of risks. Thus, the use of site-specific data may result in reduced risk estimates, and therefore possibly reduce the costs of cleanup. As described in Chapters 3 and 4, the selection of models and input parameters for the models can be negotiated, as can the exposure scenario as described in Chapter 8. EPA guidance documents clearly indicate that site-specific data has general preference over standard default factors.

9.4 References

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